PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/649,214
Filing Date:	August 26, 2003
Applicant:	Bradley Jascob et al.
Group Art Unit:	3737
Examiner:	Parikha Solanki Mehta
Title:	METHOD AND APPARATUS FOR ELECTROMAGNETIC NAVIGATION OF A SURGICAL PROBE NEAR A METAL OBJECT
Attorney Docket:	5074A-000001/COB

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

We hereby declare under penalty of perjury as follows:

1. That we are the inventors of the above-identified application.

2. That the above-identified application was conceived and reduced to practice in this country prior to January 16, 2001, the filing date of United States Pat. No. 6,352,363 to Munger (hereinafter "Munger").

3. That we are the authors of the invention disclosure attached at Exhibit A.

4. That the invention disclosure attached as Exhibit A provides evidence that the invention was conceived and reduced to practice by being built and tested prior to January 16, 2001, the filing date of Munger. In this regard, the invention disclosure identifies a "Date Conceived," a "Date Constructed," and a "Date Tested." All of these dates are before January 16, 2001, the filing date of Munger. Moreover, the figures attached to the invention disclosure represent a device that was conceived, constructed, and tested prior to the filing date of Munger.

5. Each of the dates redacted from the attached Exhibit A is prior to January 16, 2001, the filing date of Munger.

6. That this invention has never been abandoned, suppressed, or concealed.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are being made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 3/17/08 Bradley Jascob

Dated: 3·17·08 David Simon

Dated: 3/17/08 Paul Kessman

Dated: ____________ Aaron Smith

Dated:____________________

Bradley Jascob

Dated:____________________

David Simon

Dated:____________________

Paul Kessman

Dated: 3/31/2008

Aaron Smith

Exhibit A

SOFAMOR DANEK **INVENTION DISCLOSURE**

Disclosure No.	

Title of Invention	Project No. or Name
Tracking large metal objects using electromagnetics.	GoldenEye
Inventor(s) David Simon Paul Kessman Aaron Smith Brad Jascob	**Eng. Notebook No. & Pages** Paul Kessman Book #1

Date Conceived	Date Constructed	Date First Tested	Date Disclosed Outside Company
[redacted]	[redacted]	[redacted]	[redacted]

1. Describe what is new or different about the subject matter of this invention:

   Electromagnetic transmitting coils are rigidly fixed to the metal object and the effect is taken into account by the calibration process.

2. Advantages of this invention over what was done before and problems solved:

   The fields from the transmitting coils are changed by the presence of the metal. Because the metal is rigidly attached, the change is constant. By completing the calibration process with the metal in-place the effects are known.

3. Describe your idea on attached sheets, providing whatever drawings or other sketches are necessary to completely describe the idea. Copies of engineering notebook sheets may be provided. All addendum sheets must be signed, witnessed and dated.

Inventor David Simon Address: 1424 Patton DR. Boulder, CO 80303 Citizenship: Signature Date	Witness (Print/Type) Read, Witnessed and Understood Signature Date
Inventor Paul Kessman Address: 2765 Overlook Dr. Boulder, CO 80020 Citizenship: Signature Date	Witness (Print/Type) Read, Witnessed and Understood Signature Date
Inventor Aaron Smith Address: 3359 Tejon St. Denver, CO 80211 Citizenship: Signature Date	Witness (Print/Type) Read, Witnessed and Understood Signature
Inventor Bradley Jascob Address: 11580 Marshall St. Broomfield, CO 80020 Citizenship: Signature Date	Witness (Print/Type) Read, Witnessed and Understood Signature Date

Electromagnetic navigation of a large metal object or the area near it is technically challenging because the metal structure causes distortions in the magnetic field needed for navigation. This device incorporates the idea of affixing the transmitting coils to the metal and characterizing the effect during the calibration process.

The basics of electromagnetic navigation require that the strength of the transmitted fields, at any point in space, be known very accurately. Navigation is accomplished by measuring the field strength at a point in space. Once the field strengths from all transmitting coils are measured a mathematical algorithm is applied to "look-up" the single point in space that has that exact set of field strengths. Metal objects introduced into the field cause distortions to the field. During navigation, when measurements of the field are made, an incorrect position is computed due to this distortion.

The process of calibration can be accomplished by several methods. One method is to use mathematical models of the fields produced from the transmitting coils. If these models are accurate they can then be used to represent the set of "known" fields used during navigation. This method can be improved upon by accurately measuring the fields at a given set of points and applying a mathematical "fit" method to change to modeling. Using mathematical models for the transmitted fields has the disadvantage that inaccuracies in the manufacturing process of the coils can lead to incorrect field values. Additionally, when modeling the field produced by a transmitting coil set with a metal integrated into it, the models of the effects of the metal can be very complicated and may take an unreasonable amount of time for the computer to calculate.

It is possible to only measure the fields and apply a mathematical model such as a "spline" to find the fields between the measured points. This has the advantage that any inaccuracies in manufacturing are "calibrated" out. Because this method does not rely on models it automatically takes into account the effect of any metal attached to the transmitting coils.

The coils arrangement is normally known so that the mathematical models can be computed. Some methods of computing the field from a set of coils is restricted to specific types of coil geometry. The methods presented above can be applied to any generic arrangement of coils.

The model for the theoretical magnetic field produced from a rectangular coil is:

$$H(x,y,z)=\oint \frac{1}{r^3} * r \times dl$$

Stratton p 232 eqn 13

The equation for a field produced by a dipole is:

Near field : $H(\phi)=\dfrac{Idl}{4\Pi R^2}\sin\theta$ Sendra and Smith p 604 eqn 11-17

Far field : $H(\phi)=j\dfrac{Idl}{4\Pi}\left(\dfrac{e^{-j\beta r}}{R}\right)\beta\sin\theta$ Sendra and Smith p 605 eqn 11-19a

The equation for a cubic spline is

$$\frac{X_j - X_{j-1}}{6} Y''_{j-1} + \frac{X_{j+1} - X_{j-1}}{3} Y''_j + \frac{X_{j+1} - X_j}{6} Y''_{j+1} = \frac{Y_{j+1} - Y_j}{X_{j+1} - X_j} - \frac{Y_j - Y_{j-1}}{X_j - X_{j-1}}$$

Numerical Recipes p114 eqn 3.3.5

This device uses the idea of fixing the metal structure to the transmitting coils. The effect of the metal is taken into account during the calibration process. This concept is ideal for both a navigation device added in the field and a factory integrated navigation system. The idea can be applied to almost any metal object such as a fluoroscope, microscope, ultrasound hand-pieces, high-field focused ultrasound systems, CT, interoperative CT, MR, interoperative MR, and surgical robotics.

In some instances it may be desirable to create a device that is removable or can be mounted to various objects. This can be accomplished by use of a shield. The metal shield can be any shape or made of multiple shapes that create a virtual surface to shield the device. The shield should be of conductive, or semi-conductive material and it's effect on the magnetic field should dominate the effect of the item being shielded. Such a device can be constructed from materials such as sheet metal, aluminum, copper, titanium, mu-metal, or conductive mylar. The material could be solid or a mesh. A mesh design has the advantage of being much lighter than a device of solid material. A solid shield could be modified with holes or slots to reduce the weight of the shield. Electromagnetic navigation is generally done at relatively low frequencies (less than 1MHz). These frequencies represent long wavelengths that do not pass through openings undisturbed. Because of this by adding holes, or using a mesh design the performance of the shield will not be degraded.

The shield can be designed to be removable from the object being navigated or it can be an integral part of the device. With the shield as an integral part of the device the calibration process may be completed with either the shield and transmitter coils only, or with the entire device. If calibration is completed with the device a separate shield is not required. In this embodiment the effect of the device, on the transmitted fields, would be taken into account by the calibration process.

When the shield is designed to generically shield against metal objects it may be desirable to create a generic mounting mechanism for a shield and transmitter assembly. Such a mounting mechanism can be designed to fit to a variety of different device types.

The transmitter and shield assembly normally is connected to the driving circuitry via cabling. It is possible to connect the assembly through wireless transmission. Such a connection method has the advantage of being easier to setup and less obstructive in the OR. Wireless transmission can be accomplished through either analog or digital methods. Analog transmission methods such as amplitude modulation (AM), frequency modulation (FM), phase modulation (PM), can be used. Many digital communication standard exist that could be used. Standards such as wireless Ethernet and Blue-Tooth are modern methods that are gaining in popularity but almost any digital communication method can be applied.

These methods for navigating large metal objects can be applied to a number of surgical procedures such as:

Cranial biopsies, Tumor resections, Craniotomies/ Craniectomies, Thalamotomies/Pallidotomies, Spinal implant procedures such as pedicle screw placement, Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies./Sphenoid explorations, Turbinate resections, and Frontal sinusotomies, cardiac mapping procedures ,cardiac lead placements, orthepedic, and interventional radiology.

List of Claims

1. A set of transmitting coils attached to a shield for a metal object that allows that object to be navigated. The idea can be applied to almost any metal object such as a fluoroscope, microscope, ultrasound hand-pieces, high-field focused ultrasound systems, CT, interoperative CT, MR, interoperative MR, and surgical robotics.

2. A set of transmitting coils attached to a shield for a metal object that allows that object to be navigated. The idea can be applied to navigation in the large area such a navigating the interior of a Cath Lab or any Operating Room.

3. A set of transmitting coils integrated into the metal object to be navigated. The idea can be applied to almost any metal object such as a fluoroscope, microscope, ultrasound hand-pieces, high-field focused ultrasound systems, CT, interoperative CT, MR, interoperative MR, and surgical robotics.

4a. A set of transmitting coils attached to an object that allow the object to be tracked simultaneously while tracking other instruments/devices in the field.

4b. A set of transmitting coils attached to an object that allow the object to be tracked sequentially while tracking other instruments/devices in the field.

5. A universal mounting for the shield and transmitter coil assembly.

6. A method for calibrating magnetic fields that is applicable to any generic coil set arrangement.

7. A magnetic shield made of any conductive or semi-conductive materials such as sheet metal, aluminum, copper, titanium, mu-metal, or conductive mylar.

8. A magnetic shield made of a mesh of material.

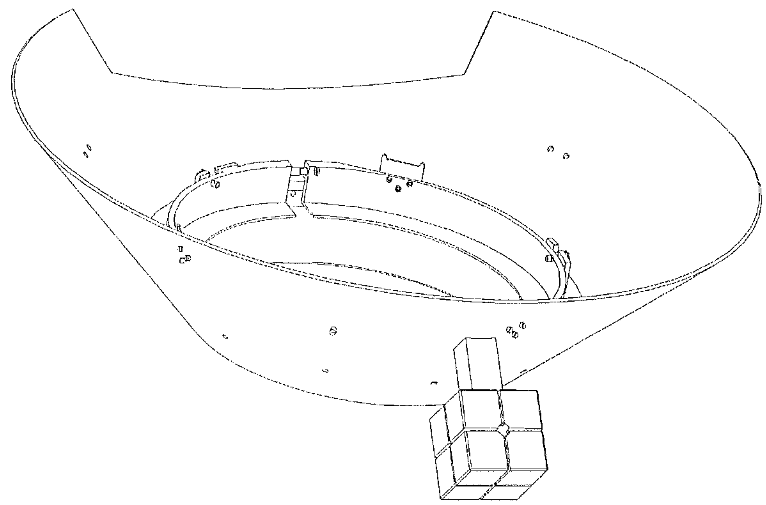
9. A magnetic shield with holes or slots to reduce weight.

10. A method for calibrating generic coil set geometries

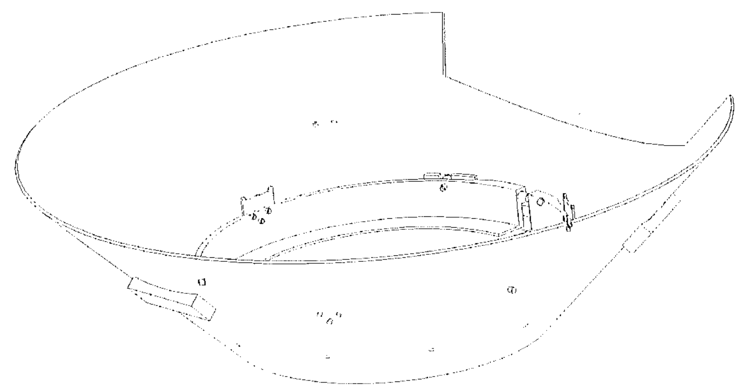
11. A method for calibrating a set of transmitting coils with a shield attached.

12. A wireless connection to the electromagnetic transmitter.

Shield with extended transmitter coils
Figure #1



Shield with integrated transmitter coils
Figure #2



Shield and transmitter attached to FlouroScope
Figure #3